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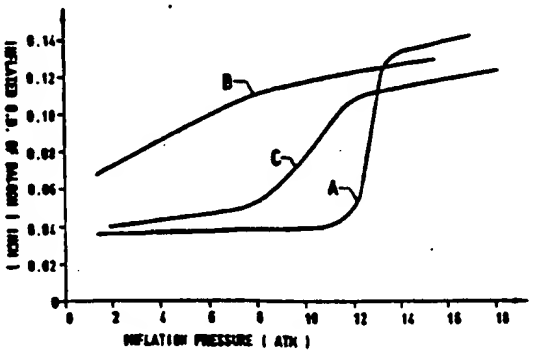
(54) Inflatable member having elastic expansion with limited range.

(57) An intravascular catheter (10) such as an angioplasty catheter having a catheter shaft (11) with an expandable tubular element (13) on its distal end which upon inflation to an internal pressure at or above a threshold pressure expands in a manner which is related to the internal pressure. The maximum transverse dimension of the expandable tubular element (13) is generally not greater than the maximum transverse dimension of the catheter shaft (11). Preferably, the expandable tubular element (13) is formed of a heat shrinkable polymeric material such as a polyolefinic ionomer.

FIG. 5



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dilate a stenosis, oxygenated blood in the artery or the aorta or both, depending upon the location of the dilatation catheter within the coronary anatomy, is forced to pass through the proximal perfusion ports, through the inner lumen of the catheter and out the distal perfusion ports. This provides oxygenated blood downstream from the inflated balloon to thereby prevent or minimize ischemic conditions in tissue distal to the catheter. The perfusion of blood distal to the inflated balloon allows for long term dilatations, *e.g.* 30 minutes or even several hours or more. This catheter has likewise been highly praised by the medical profession and has met with much commercial success. Commercially available perfusion type dilatation catheters include the STACK PERFUSION™ and the ACS RX PERFUSION™ Dilatation Catheters which are sold by ACS.

The balloons for prior dilatation catheters utilized in angioplasty procedures generally have been formed of relatively inelastic polymeric materials such as polyvinyl chloride, polyethylene, polyethylene terephthalate and polyolefinic ionomers. Nylon has been mentioned in the literature as an alternative inelastic material from which dilatation balloons can be made, but there has not been much commercial use of this material. The aforementioned prior art balloons are characteristically relatively inelastic so that upon inflation with inflation liquid there is relatively little expansion of the balloon with increased internal pressures, even at very elevated levels. However, when the prior art balloons were deflated, the inelastic balloon material did not shrink or contract, so as a result, the deflated profiles of the prior art balloons were relatively large. In an effort to reduce the deflated profiles of the prior art balloons made formed polyethylene, polyvinyl chloride and polyolefinic ionomers. very frequently they would be heat formed so as to wrap around inner members extending through the interior of the balloons. However, balloons formed of polyethylene terephthalate were not readily heat formed, with the result that, when a vacuum was pulled on the balloon, wings were formed which extend outwardly presenting a relatively large profile.

What has been needed and heretofore unavailable is a thin walled inflatable member for intravascular catheters which upon inflation exhibits a controlled elastic expansion but which does not expand significantly beyond a particular pressure level. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

This invention is directed to an inflatable member such as a balloon which exhibits upon inflation a substantial elastic expansion within a first pressure range and which is considerably less compliant at pressures beyond the first pressure range. Upon deflation, the inflatable member contracts by elastic recoil to a diameter much smaller than the inflated diameter.

Disclosed herein is an inflatable member having an expandable wall portion which at internal pressures within a first pressure range exhibits substantial elastic expansion and within a second pressure range, higher than the first pressure range, exhibits relatively little expansion.

The inflatable member of the invention is a tubular member which when inflated exhibits a relatively high rate of elastic expansion within a first range of internal pressures and a relatively low rate of expansion, i.e. is much less compliant, at pressures within a second range of internal pressures higher than the first range. In one presently preferred embodiment, during the initial stage of inflation, when the internal pressures are below the first pressure range, the inflatable member or balloon is relatively noncompliant and experiences relatively little expansion, but when the internal pressures reach the first pressure range, the inflatable member expands elastically at a relatively high rate until the pressure enters a second pressure range at which point the inflatable member becomes relatively noncompliant and the expansion rate thereof is quite low. The expansion at failure is usually less than 25% and preferably less than 10% of the maximum inflated diameter at the end of the elastic expansion. Upon deflation of the inflatable member, it contracts to a diameter much smaller than the inflated diameter by means of elastic recoil.

In the deflated condition the inflatable member of the invention preferably has outer dimensions which are essentially the same as or not much larger than adjacent portions of the catheter shaft in order to present a relatively smooth outer surface which greatly facilitates the insertion and advancement of the inflatable member through the vascular system of a patient and through stenotic region of the patient's artery. When subjected to a vacuum, the inflatable member forms very small wings or essentially no wings at all which helps the passage of the inflatable member through the patient's blood vessels and through stenoses.

The inflatable member of the invention may be formed of heat shrinkable thermoplastic material, particularly a radiation cross-linked polymer material, which has been thermally treated at a temperature of not more than about 50° C above and not more than about 50° C below the crystalline melting point of the polymer to provide the requisite expansion of the present invention. In one presently preferred embodiment the inflatable

invention, the initial diameter of the deflated inflatable member is larger than the diameter of the inflatable member which has not been preexpanded and heat shrunk. However, upon applying a vacuum to the interior of the inflatable member in accordance with the present invention, it has been found to readily form small wings which tend to wrap around any inner tubular member to reduce the deflated profile of the catheter. The relatively small wings allow the inflatable member to expand upon inflation without applying significant shear stress to the stenotic region. There is much evidence demonstrating that high shear stress on the lesion can cause dissections which can interfere with blood flow through the arterial passageway and that high shear stress can develop an arterial lining on which restenosis is rapid.

In yet another embodiment of the invention, means are provided to heat the inflatable member after it has been inserted into a patient's vasculature or other body lumen to reduce the pressure required to inflate the inflatable member to an operable size. Suitable systems for heating the inflatable member by radio frequency energy are disclosed in copending applications Serial No. 07/351,777, filed May 15, 1989 and Serial No. 07/521,337, filed May 9, 1990 which are incorporated herein.

The inflatable members of the invention may also be employed in dilatation catheters used in other body lumens such as the catheter described in copending application Serial No. 07/483,397, filed February 14, 1990 which is adapted to dilate a prostatic urethra subject to hyperplasia.

Catheters having inflatable members in accordance with the invention may also be used to deliver expandable tubular elements mounted on the exterior of the inflatable member. Examples of such expandable tubular elements include stents and tubular elements which accept drug or therapeutic fluid and which expel drugs or therapeutic fluids upon the expansion of the inflatable member, *i.e.* the wall of the tubular element thins upon expansion thereby driving out the fluid.

These and other advantages of the invention will become more apparent from the following detailed description thereof when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view partially in section of a dilatation catheter embodying features of the invention.

FIG. 2 is a transverse cross-sectional view of the catheter shown in FIG. 1 taken along the lines 2-2.

FIG. 3 is a transverse cross-sectional view of the catheter shown in FIG. 1 taken along the lines 3-3.

FIG. 4 is an elevational view of the distal portion of the catheter shown in FIG. 1 with the inflatable section in an inflated condition.

FIG. 5 is a graphical representation of the relationship of the outer diameters of inflatable members of the invention with respect to the internal pressure.

FIG. 6 is a longitudinal cross-sectional view of the distal portion of a dilatation catheter embodying features of the invention having means to releasably secure a guidewire within the catheter.

FIG. 7 is a longitudinal cross-sectional view of a distal portion of a dilatation catheter as shown in FIG. 6 wherein the means to releasably secure a guidewire within the catheter is engaged with the guidewire.

FIG. 8 is a longitudinal cross-sectional view of a distal portion of a dilatation catheter embodying features of the invention having means to heat the inflatable section.

FIG. 9 is a transverse cross-sectional view of the distal portion of the dilatation catheter shown in FIG. 8 taken along the lines 9-9.

FIG. 10 is a transverse cross-sectional view of the distal portion of the dilatation catheter shown in FIG. 8 taken along the lines 10-10.

FIG. 11 is a longitudinal view of a distal portion of a dilatation catheter embodying features of the invention having an expandable tubular element which is capable of absorbing drugs or other therapeutic fluids mounted on the exterior of the inflatable section of the catheter.

FIG. 12 is a transverse cross-sectional view of the embodiment shown in FIG. 11 taken along the lines 12-12.

FIG. 13 is a longitudinal cross-sectional view of the embodiment in FIG. 11 with the inflatable section in an inflated condition.

FIG. 14 is a longitudinal cross-sectional view of the distal portion of a steerable, fixed-wire dilatation catheter having an inflatable section which embodies features of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Reference is made to FIGS. 1-3 which illustrate a dilatation catheter 10 embodying features of the invention. The dilatation catheter 10 generally includes a catheter shaft 11 with an inflatable tubular section 12 on the distal extremity of the catheter and an adapter 13 on the proximal end thereof and. The catheter shaft 11 has an outer tubular member 14 which is provided with the inflatable tubular section 12 and an inner tubular member 15 which is disposed within the outer

catheter and the guidewire can be advanced together as a unit through an artery and a stenosis within the artery as described in U.S. Patent 4,932,959 (Horsewski *et al.*) which has been incorporated herein. In the embodiment shown in FIGS 6 and 7, the inner tubular member 15 is provided with a thin wall section 22 which is designed to collapse onto a guidewire 18 disposed within the inner lumen 17 at a pressure less than the pressure range in which the inflatable member 12 expands elastically. In this manner, the annular inflation lumen 16 of the catheter may be subjected to a first pressure much less than the pressure range effecting elastic expansion to cause the thin wall section 22 to collapse about the guidewire 18 thereby releasably securing it within the catheter. The combined catheter and guidewire assembly has much better pushability than either the catheter or the guidewire alone so the assembly can be more easily advanced through a tight stenosis. Once the inflatable portion 12 of the dilatation catheter 10 is disposed across the stenosis, the pressure of the inflation fluid within the catheter may then be increased to a level above the threshold level to inflate the inflatable section 12 to the desired size to dilate the stenosis. After the dilatation, the pressure of the inflation fluid may be reduced to a level which allows the inflated section 13 to return to its original size. If no further dilatations are to be done, the pressure may be reduced to even lower levels to allow the thin wall section 22 of the inner tubular member 15 to return to its original position, thereby releasing the guidewire 18 therein.

FIGS. 8-10 illustrate yet another embodiment of the invention wherein the inflatable member 12 is heated while it is being inflated within the patient in order to reduce the pressure range in which substantial expansion of the inflatable member occurs in the elastic mode. In this embodiment, a heater coil 23, which is electrically connected to an electrical power source (not shown), is disposed about the inner tubular member 15 which extends through the interior of the inflatable section 12. A thermocouple 24 may be provided to sense the temperature of the inflatable section 12 or the inflation fluid therein so that the control means (not shown) may compare the temperature sensed with a desired temperature limit and adjust the electrical power from the source accordingly to control the temperature as desired. The pressure and temperature relationship with respect to the inflated diameter of the inflatable section are readily determined before the insertion of the catheter within a patient's vasculature so that the desired inflated diameter of the inflatable section can be obtained by the physician by noting the pressure and adjusting the temperature of the inflatable wall portion of the balloon or vice versa. Generally, a rise in the temperature of the wall of the inflatable section will lower the pressure range wherein there is a substantial elastic expansion of the inflatable section as shown in FIG. 5 and reduce somewhat the rate of pressure increase. Once the inflatable member has been inflated above the pressure range for elastic expansion, the temperature of the inflatable member can be allowed to return to body temperature and the angioplasty or other procedure can be completed in a conventional fashion. The catheter shaft 11 of this embodiment differs somewhat from that shown in the prior embodiments in that it has two inner lumens extending side-by-side therein, a first or inflation lumen 25 which is crescent shaped in transverse cross-section and a second or guidewire receiving lumen 26 which is circular in cross-section as shown in FIG. 9. The inflation section 13 is shown in the inflated condition in phantom in FIGS. 8 and 10. In this embodiment proximal and distal perfusion ports 27 and 28 respectively are provided so, that upon inflation of the inflatable section 13 to dilate a stenosis, oxygenated blood will flow through the proximal perfusion ports 27 into the inner lumen 17 and out the distal perfusion ports to reduce the possibility of ischemic conditions developing in tissue distal to the catheter.

FIGS 11-13 illustrate another embodiment of the invention wherein the catheter 10 is adapted to deliver drugs to a desired location within a patient's body lumen, such as a blood vessel. In the embodiment shown a tubular element 30 is capable of absorbing liquid drugs or therapeutic fluids is disposed about the inflatable section 12 of the invention. Inflation of the inflatable section 13 increases the diameter of the tubular element 30, compressing the wall thereof and driving out fluid absorbed therein to deliver the drug or therapeutic fluid to the desired location within the patient's body lumen. In an alternate embodiment (not shown) a second inflatable member having a plurality of small apertures through the wall thereof is disposed about the inflatable section 12 with liquid drugs or therapeutic fluids disposed between the inflatable section 12 and the second inflatable member so that inflation of the inflatable section will drive the liquid through the apertures in the outer second inflatable member. The number and size of the apertures in the wall of the outer balloon wall are determined for the most part by the nature of the therapeutic fluid, *e.g.* viscosity and the like, and the amount of fluid to be delivered and the rate at which it is to be delivered.

A steerable, fixed wire dilatation catheter 31 is depicted in FIG. 14 which has a tubular shaft 32 having a proximal portion (not shown) formed of stainless steel or superelastic Nitinol hypotubing

jected to internal pressure. Other modifications include forming the inflatable section of an outer tubular member in accordance with the invention and secure the inflatable section to a catheter shaft of different material or the same material with differing properties. In some instances it may be desirable to inflate the inflatable section before the catheter is introduced into the vascular system of the patient in order to reduce the internal pressure required for the initial expansion of the inflatable section. This preexpansion also decreases the rate of increase of the expansion, but does not substantially change the range of pressure in which the elastic expansion occurs. A wide variety of other modifications and improvements can be made to the invention without departing from the scope thereof.

Claims

1. An inflatable member having an expandable wall portion which at internal pressures within a first pressure range exhibits substantial elastic expansion and within a second pressure range, higher than the first pressure range, exhibits relatively little expansion.

2. The inflatable member of claim 1 wherein the expansion after the first pressure range does not exceed about 25% of the inflatable wall portion at the end of the first pressure range.

3. The inflatable member of claim 1 wherein the expansion after the first pressure range does not exceed about 10% of the inflatable wall portion at the end of the first pressure range.

4. The inflatable member of claim 1 wherein the expansion of the expandable wall portion after the first pressure range is essentially linear with respect to the pressure.

5. The inflatable member of claim 5 wherein the expandable wall portion is thermally treated at a temperature within 50° C of the crystalline melting point of the polymeric material.

6. The dilatation member of claim 5 is formed of polymer materials which contains up to 30% of polymers other than oleophilic ionomers.

7. An inflatable member having a wall portion which at internal pressures above a threshold pressure exhibits a limited, controllable expansion directly related to the internal pressure therein which does not exceed about 50% of the expansion of the inflatable wall portion at the threshold pressure.

8. An elongated intravascular catheter comprising:
   a) an elongated catheter shaft having proximal and distal extremities and an inner lumen extending therein;
   b) an inflatable section on the distal extremity of the catheter shaft having an interior in fluid communication with the inner lumen of the catheter shaft and exhibiting upon inflation to an internal pressure within a first pressure range substantial elastic expansion and within a second pressure range, higher than the first pressure range, very little expansion; and
   c) means to direct inflation fluid to the interior of the inflatable section.

9. The intravascular catheter of claim 8 wherein the catheter shaft has an inner tubular member with a guidewire receiving inner lumen extending therein which extends through the interior of the inflatable member.

10. The intravascular catheter of claim 9 wherein the internal tubular member has a portion thereof collapsible at a pressure less than the first pressure range and wherein heating means are provided to increase the temperature of the expandable wall portion to decrease the first pressure range.

11. The device of claims 1 or 8 wherein the inflatable member is formed of radiation cross-linked polymeric material or heat shrinkable polymeric material.

12. The device of claim 11 wherein the radiation cross-linked polymeric material is a polyolefinic ionomer selected from the group consisting of sodium, zinc and lithium ionomers.

13. The device of claims 1 or 8 wherein the inflatable section exhibits elastic recoil upon deflation.

14. The dilatation catheter of claim 6 wherein the inflatable member is inflated at the thermal treatment temperature, cooled and then heat shrunk.

15. The dilatation catheter of any one of the preceding claims wherein the deflated transverse dimensions of the inflatable member are not more than about 10% greater than the transverse dimension of the adjacent catheter shaft.

cing step.

21. An inflatable dilatation member which upon inflation has a relatively high rate of expansion to a first diameter within an first pressure range and a relatively low rate of expansion to a second diameter larger than the first diameter within a second pressure range higher than the first pressure range and which upon deflation exhibits elastic recoil to a third diameter smaller than the first and the second diameters.

22. The dilatation member of claim 18 wherein said member is formed of one or more oleophilic polymers selected from the group consisting of zinc and sodium ionomers.

23. A method of making an inflatable dilatation member comprising:
    a) extruding a tubular product formed of an olefinic ionomer at an elevated temperature;
    b) cool the extruded tubular product after its extrusion to obtain a relatively amorphous structure therein;
    c) irradiate at least a portion of the amorphous tubular product which will form the inflatable member; and
    d) heat treating the portion of the tubular product which will form the inflatable member at a temperature between about 50°C above and about 50°C below the crystalline melting temperature.

24. The method of claim 23 including the steps of expanding the irradiated portion of the tubular product to a first outer diameter by injecting inflation fluid into the interior of the irradiated portion at an elevated temperature to cause the expansion of the irradiated portion, cooling the expanded portion of the tubular product and then heat shrinking the expanded portion of the tubular product to a second outer diameter much smaller than the first outer diameter.

25. The method of claim 23 wherein the extruded tubular product is stabilized at a temperature between about 40°C to about 80°C for about 2 to about 6 hours before the irradiation thereof.

26. The method of claim 23 wherein the extruded tubular product is quenched upon exiting from the extruding operation in a bath at a temperature of about 40°F to about 60°F.

27. The method of claim 23 wherein the extruded tubular product is irradiated with about 50 to about 70 Mrads of gamma radiation.

28. The method of claim 27 wherein the irradiated portion of the extruded tubular product is subjected to a temperature of about 230°C to about 250°C.and an inflation pressure of about 50 to about 85 psi to form into an inflated balloon.

29. The method of claim 28 wherein the inflated balloon is cooled and then subjected to a temperature of about 50°C to about 75°C for about 5 to about 60 minutes to heat shrink the expanded balloon from a first diameter to a smaller second diameter.

30. The method of claim 23 wherein the olefinic ionomer is selected from the group consisting of sodium, zinc and lithium olefinic ionomers.

FIG. 5

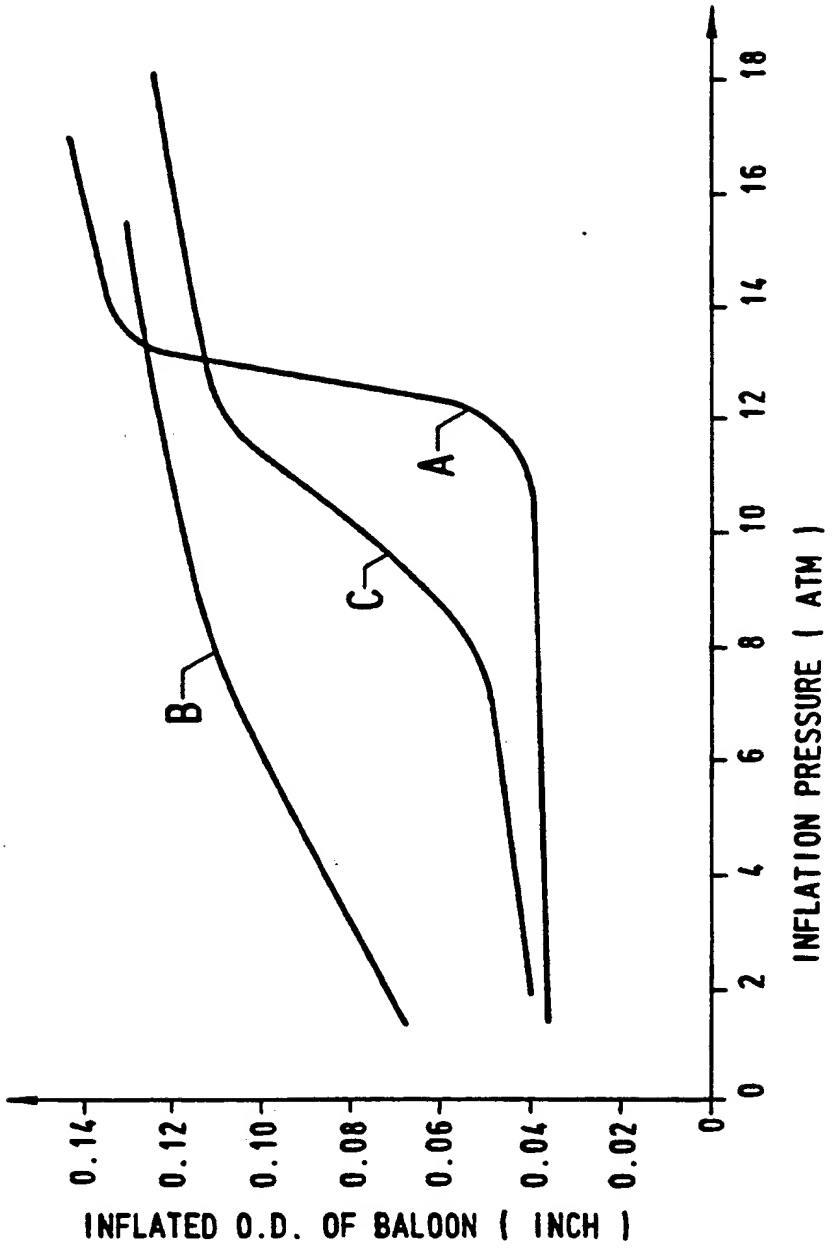

INFLATED O.D. OF BALOON (INCH)
0.14
0.12
0.10
0.08
0.06
0.04
0.02
0
2
4
6
8
10
12
14
16
18
INFLATION PRESSURE (ATM)
A
B
C

FIG. 8

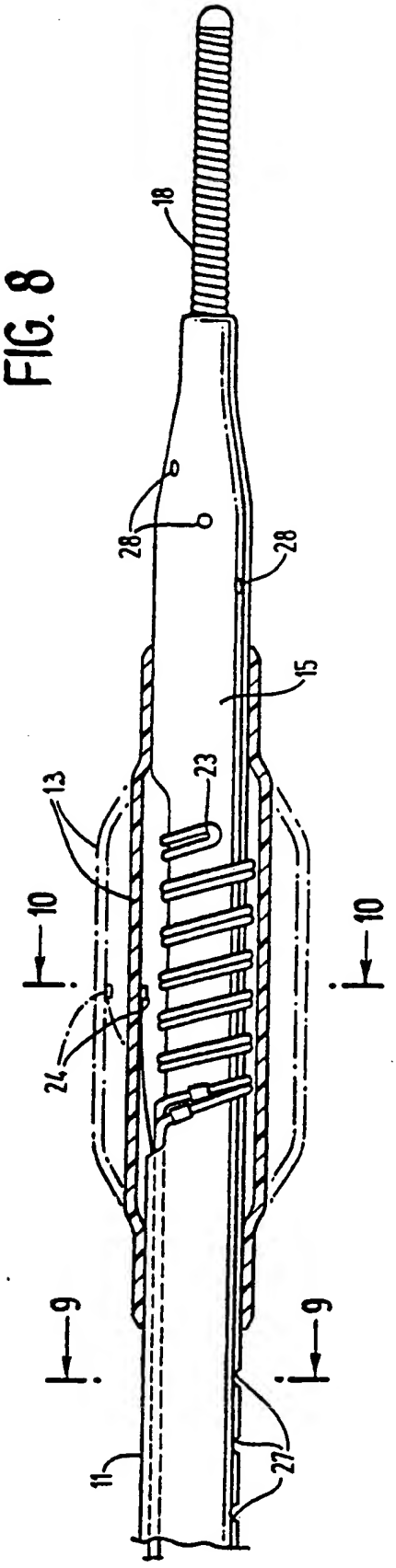


FIG. 10

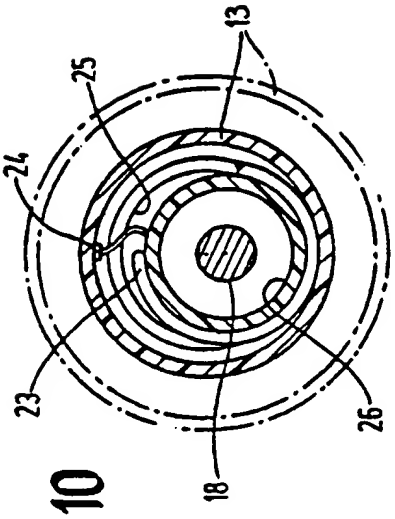
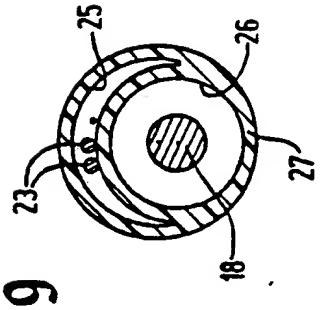


FIG. 9



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EUROPEAN SEARCH REPORT

Application Number
EP 92 11 5587

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP-A-0 197 787 (AMERICAN MEDICAL SYSTEMS, INC.) * page 7, paragraph 2 * * page 8, last paragraph - page 9, paragraph 1 * * page 12, line 14 - line 17; figures 1,3A,6 *	1-4,7,13	A61L29/00
Y		8-11	
A		17,18, 21,23	

D,Y	US-A-4 932 959 (HORZEWSKI ET AL.) * column 3, line 26 - column 4, line 41; figures 1-3 *	8-11	
A		1,5,6, 17,18	

D,A	US-A-5 035 694 (KASPRZYK ET AL.) * column 7, line 40 - line 45; claim 1; figures 1,4 *	1,5,6,8, 9,11,13, 14, 16-18,20	TECHNICAL FIELDS SEARCHED (Int. Cl.5)
	---		A61L
A	GB-A-2 008 140 (BAXTER TRAVENOL LABORATORIES INC.) * claims 1,9-11 *	1,5,8, 11,12, 17,18, 22,23,30	A61B A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	25 NOVEMBER 1992	ROLAND A.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
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